510(k) Summary
Raphael Pedicle Screw System
Premarket Notification

SUBMITTED BY	Accel Spine 14901 Quorum Dr. Ste. 125 Dallas, TX 75254
ESTABLISHMENT REGISTRATION NUMBER	3009051471
OWNER/OPERATOR NUMBER	10035914

AUG 2 0 2013

CONTACT PERSON	Aekta Patel General Counsel Accel Spine Phone: 214-545-5833 Fax: 888-831-4892
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Email: lpeterson@kaedonconsulting.com Phone: 512-507-0746
DATE PREPARED	July 24, 2013
CLASSIFICATION NAME	Spondylolisthesis Spinal Fixation, Spinal Pedicle Fixation
DEVICE CLASS	Class II
REGULATION NUMBER	888.3070 (Product Code MNH, KWP, MNI)
COMMON NAME	Pedicle Screw Spinal Fixation System
PROPRIETARY NAME	Raphael Pedicle Screw System
IDENTIFICATION OF PREDICATE DEVICE(S)	Dio Medical Rexious Spinal Fixation System (K113324, K111362, K100765)

DEVICE DESCRIPTION
The Raphael Pedicle Screw System is a top-loading multiple component, posterior spinal fixation system that consists of pedicle screws, rods, hooks, set screws, connectors, and a transverse (cross) linking mechanism. The Raphael Pedicle Screw System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion.

INDICATIONS
The Raphael Pedicle Screw System is a posterior pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S I vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Raphael Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The Raphael Hook System is intended for use as a posterior, noncervical, nonpedicle system indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma(i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The Raphael Hook System can be used in conjunction with Raphael Pedicle Screw System.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS
The purpose of this Special 510(k) is to obtain clearance to market the subject device as the Raphael Pedicle Screw System. The subject device was previously cleared as the Dio Medical Rexious Spinal Fixation System (K113324, K111362, K100765). Documentation demonstrating the legal right to distribute the Raphael Pedicle Screw System is maintained at Accel Spine.

The subject device is identical to the previously cleared Rexious System in terms of indications for use, device dimensions, instrumentation, manufacturing process, cleaning/sterilization process and labeling. The System implant components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

DISCUSSION OF NON-CLINICAL TESTING
Non-clinical testing was not performed as part of this submission.

CONCLUSIONS
The subject device is identical to the predicate device in terms of indications for use, device dimensions, instrumentation, manufacturing process, cleaning/sterilization process and labeling. Documentation was provided as part of this Special 510(k) to demonstrate that the Raphael Pedicle Screw System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

Ms. Aekta Patel
General Counsel
Accel Spine
14901 Quorum Drive, Suite 125
Dallas, Texas 75254

Re: K132365
Trade/Device Name: Raphael Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: July 24, 2013
Received: July 30, 2013

Dear Ms. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K132365

Device Name: **Raphael Pedicle Screw System**

Indications for Use:

The Raphael Pedicle Screw System is a posterior pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S I vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132365